

In the January 7, 2002 Office Action, the Examiner required restriction under 35 U.S.C. § 121 to one of the following allegedly independent and distinct inventions:

- I. Claims 1-2, 7-9, and 12, drawn to a method to identify cancer therapeutic by identifying a protein which is expressed in the target cancer cell and determining if the protein is immunogenic and to design a cancer vaccine using the protein, classified in class 514, subclass 02.
- II. Claims 1, 3 8, and 10-16, drawn to a method to identify cancer therapeutic by identifying a polynucleotide which is expressed in the target cancer cell and delivering the peptide encoded by the polynucleotide to a subject and further administering cytokine and/or co-stimulatory molecule to induce an immune response against a target cell, classified in class 514, subclass 44.
- III. Claims 1, 4, and 17-20, drawn to a method to identify cancer therapeutic by administering to the subject immune effector cells reactive with immunogenic protein, classified in class 424, subclass 93.21.
- IV. Claims 1, 5-6, 21-24, drawn to a method to identify cancer therapeutics by administering monoclonal antibodies reactive with immunogenic protein, classified in class 530, subclass 388.1.

Applicant's undersigned attorney hereby elects Group I with traverse.

Applicants traverse the Restriction Requirement as confusing based upon a fair reading of the claims. Clarification from the Patent Office, and a fair opportunity to respond, is requested.

In particular, Applicants note that the restricted subject matter of Group I and Group II is directed to a distinction not found in the restricted claims. In Group I, the

method of Claim 1 is characterized as *"identifying a protein"* and in Group II, the method of Claim 1 is characterized as *"identifying a polynucleotide"*. However, Claim 1 actually requires a first step of *"identifying a polynucleotide"* and a second step of *"determining the protein corresponding to the polynucleotide"*. It is not proper to require restriction between Groups I and II divided by the steps of the linking claim.

The Patent Office's distinctions in the restriction between the first and second step of Claim 1 is further confused by the claims assigned to each Group. Group I is further characterized as being drawn to a cancer vaccine *"using the protein"* and then includes Claims 2, 7-9, and 12. However, Claim 2 is directed to the administration of the immunogenic protein in a *gene delivery vehicle*! Thus, Claim 2 seems to fall within Group II; Group II is directed to *"delivering the peptide encoded by the polynucleotide to a subject."*

Not included in Group I, Claim 3 provides the further limitation that the immunogenic protein is administered in an antigen presenting cell (APC). An APC may be loaded by either pulsing peptides (See page 46, lines 18-29) or delivery of polynucleotides. (See page 45, lines 25-30). Hence, Claim 3, is generic to both the methods of Groups I or II.

Claim 7, an independent claim, is not limited in any fashion to the mode of *"identifying an amino acid"* nor to any mode of delivery. The limitation of Claim 7, *"identifying an amino acid sequence"* can be readily satisfied by the determination of a polynucleotide sequence. Thus, Claim 7 falls within both Groups I and II. As to Claims

11, it is not understood why it was assigned to Group II, given that Claim 8 is considered a linking Claim between Groups I and II, and it provides additional limitations as found in Claim 1, also admitted to be a linking claim.

No fee is deemed necessary in connection with the filing of this communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

Respectfully submitted,

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Date

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